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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 21

Application Number: 09/214,047
Filing Date: July 12, 1999
Appellant(s): MULLER, DIETER

Richard M. Beck, Reg No. 22,580
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on July 02 2002.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct. However, the rejection of claim 5 under 35 USC § 112, 2nd paragraph has been withdrawn.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1, 3-5 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7). Appellant's brief includes a statement that claims 1, 3-5 do not stand or fall together, but provides no reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,162,037	Whitson-Fischman	11/92
5,830,140	Dillinger et al	11/98
DE 3,419,055	Brenner	11/85

Schoni et al, "Efficacy Trial of Bioresonance in Children with Atopic Dermatitis" International Arch Allergy Immunol. Vol 12, (march 1997), pp.:238-246

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of "pharmaceutical administration form in form of an electromagnetic memory" is vague, because in the pharmaceutical art "a pharmaceutical administration form" is considered a dosage form that is administrable by any of the known routes of administration. In the instant case "an electromagnetic memory" which is claimed as a pharmaceutical form is indefinite because it is not an acceptable term in the art, and is not recognized as a pharmaceutical form. Further, it is not clear what "a pharmaceutical administration form" encompasses. The metes and bounds of such recitation is not clear.

The recitation of "bioresonance spectrum" is indefinite. The specification further fails to clearly define what a bioresonance spectrum is? The definition set forth in page 2 of the specification is ambiguous. Furthermore, the art does not provide a clear definition of such spectrum, thus the recitation as a whole is indefinite.

Claim 3 is vague. It is not clear what is meant by "to a skin well-tolerated adhesive tape whose projecting marginal strips are suited to be adhered to the skin of a patient." what are the metes and bounds of " well-tolerated adhesive tape" or "suited to be adhered to skin?" Such recitations appear to be relative in nature and the metes and bounds thereof are not well defined. Furthermore, parenthetical references to the drawings is renders the claims indefinite, because the claims must stand on their own.

Claims 4-5 respectively recite the limitations "predetermined factor" and "predetermined amplification." Such recitations appear to be relative, the metes and bounds of which is not clear.

Claim 5 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear for what treatment or what type of disease are the instant pharmaceutical forms employed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of using a bioresonance apparatus unit, does not reasonably provide enablement for methods of making or using a pharmaceutical administrable form for treating various disease states. Furthermore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim.

In particular, the specifications fails to enable the skilled artisan to practice the invention without undue experimentation. As held by *ex parte Forman* (230 USPQ 546, BdPatApp & Int.) and *In re Wands* (858 F.2d 731, 8 USPQ2d 1400, 1404, Fed. Cir. 1988) provide several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation.

First, the state of the prior art concerning methods of bioresonance therapy is controversial and speculative. In fact, the proponents of such alternative therapy believe that the physical science is the science of dead material and thus incapable of commenting on the effects of biological phenomena such as bioresonance therapy or other methods of acupuncture in treatments of various disease states (Schoni at page 245, 1st para. Lines 1-6).

Further, the pharmacological effects and benefits of such types of therapeutic approaches have not been described by scientific methodologies (Id. at page 245, last para. Lines 1-22). Therefore, neither the art, nor the specification provide adequate enablement for the claimed therapeutic utility of the instant invention.

Second, there is no correlation between the instantly claimed bioresonance spectrum and those described in the art. It has been described in the homeopathic art that in bioresonance therapy "the pathological electromagnetic wave patterns" which is different for specific disease state are corrected when converted to "normalized electromagnetic waves", using a specific analyzing apparatus such as BIOCOM ™. (see instant specification at page 4, para 4 – page 5, para. 6; also see Schoni at page 238, 1st para. – page 239, end of the 1st para.).

Accordingly, the waves from one part of the body are taken up by a brass electrode, and analyzed in a separator of said apparatus. During this process, the pathological waves are separated from the normal (healthy) waves and then said pathological waves are reversed electronically by said separator and finally transmitted back to the patient by an exit electrode to produce its therapeutic effects (see Schoni et al 239, 1st para and fig 1.).

Hence, the bioenergy that is normalized during a treatment course of bioresonance therapy **is actually generated within the body of the patient**, and then corrected by an external apparatus filtering the pathological bioenergy. (see Schoni et al p.245, and specification page 5). In fact, the recitation of "bioresonance" requires the

element of "bio" referring to biology or a biological entity. Thus, "bioresonance" conveys a direct association of the intended resonance with a living organisms.

In the instant case, there is no correlation between applying the bioresonance spectrum obtained of a medical compound (a dead entity) and its effects on a biological receptor system, because this approach, in itself, is in contrary to the principles of the bioresonance theory. Namely, there is no pathological bioenergy associated with the medical compound to be filtered. Thus, it is not clear how a bioresonance spectrum of a medical compounds suited to have direct effects on biological receptors are made. How can one verify the spectrum on a magnetic tape is indeed a bioresonance spectrum of a medical compound.

Furthermore, there is no predictability in the art that the claimed bioresonance spectrum obtained in the form of a magnetic tape can correct the pathological waves of a patient (as in accord with the bioresonance theory), neither is there any predictability in the mechanism of action of said spectrum on biological and cellular receptors. To elaborate on this element, Examiner points out that specification is absolutely silent about how such spectrum can influence the internal receptor system and improve a diseased tissue. What is the mechanism associated with the claimed therapeutic method, and what disease can actually be treated?

In addition, there is no prior knowledge in the art explaining the normal frequency of human's bioenergy, and the differences thereof with various types of pathological diseases. Thus, one skilled in the art would not be able to determine the efficacy of such therapy without undue experimentation.

Finally, the working examples do not provide any scientific guidance of how the instant pharmaceutical form exerts its pharmacological benefits on the receptor system. In fact, the bioresonance therapy, as reported by Schoni et al, provides no therapeutic effects. Such conclusion is consistent in the short- or in the long-term management of specific skin allergy or atopic dermatitis in children (see Schoni's abstract and discussion).

Moreover, the specification provide no guidance as to how one skilled in the art would go about treating a specific disease within the scope of the presently claimed invention. Nor is there any guidance provided to a specific protocol that can be utilized in order to prove the efficacy of the presently claimed pharmaceutical form in treating the claimed disease states.

Accordingly, undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed invention. Thus, the specification does not enable any person skilled in the art to make and use the invention and further practice it within the scope that is instantly claimed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371□ of this title before the invention thereof by the applicant for patent.

Claim 1 rejected under 35 U.S.C. 102(b) as being anticipated by Berner et al DE 3419055.

The instant claim is directed to a pharmaceutically administrable form comprising a bioresonance spectrum of a medical compound. Further, the instant claim appears to be drafted in the form of a product-by-process claim. To the extent that the instant products are magnetic tapes containing electromagnetic spectrum, the claims are rejected.

Product-by-process claims are not limited to their process methods. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself (see MPEP 2113). The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

In the instant case, Brenner discloses a magnetic foil sheet for biophysical therapy comprising a plastic matrix and magnetic particles (see abstract). Therefore, Brenner meets the limitations set forth in the instant claim.

Claims 1, 3 and 5 rejected under 35 U.S.C. 102(b) as being anticipated by Whitson-Fischman US Patent 5,162,037.

Whitson-Fischmann discloses methods of impregnating a topical patch comprising a homeopathic medicament and a magnetically permeable ingredient that is magnetized (see abstract, col 6 lines 35-68, col 7 lines 1-30). Whitson-Fischmann

further discloses methods of using his patch by aligning it near a selected acupuncture point on the patient's skin (see col 9 lines 29-61, col 40 lines 16-40). Accordingly, since the instant products are viewed to be magnetic tapes containing electromagnetic spectrum, the claims are rejected by Whitson-Fischmann.

Claims 1, 3-5 rejected under 35 U.S.C. 102(e) as being anticipated by Dillinger et al US Patent 5,830,140

Dillinger et al discloses the use of a bioresonance apparatus to register the substance specific or body specific energetic information in the form of electromagnetic spectra to produce a homeopathic medicament composition (see col 1 lines 1-65, col 3 lines 40-67, col 4 lines 65-67). Dillinger discloses that the characteristic oscillation information after processing through the bandpass filter can be superimposed on an oscillating 10Hz magnetic field from the generator (see col 7, lines 1-5; col 7, lines 20-35). Therefore, Dillinnger discloses the instant frequency ranges. Accordingly, Dillinger et al meet the limitations set forth in the instant claims.

(11) Response to Argument

Appellant' arguments in the response filed on July 02, 2002, in the Appeal Brief, Paper No. 20, have been fully considered, but are not found persuasive.

- **Claim 1 should stand rejected under 35 U.S.C. 112, second paragraph, because the recitation of "pharmaceutical administration form in form of an electromagnetic memory," and "bioresonance spectrum," render the claim as a whole indefinite.**

First, Appellant argues that expression of "pharmaceutical administration form" is misinterpreted by the Examiner. In response, Examiner states that the 35 USC 112 second paragraph requires sufficiently clear meaning of the claimed terms to the extent

that any departure from common usage would be so understood by a person experience in the field of the invention. *Multiform Desicants Inc. v. Medzam Ltd.* 133 F.3d 1473, 1477. 45 USPQ2d 1429, 1432 (Fed, Cir 1998).

In the pharmaceutical art "a pharmaceutical administration form" is viewed as any dosage form known in the art which can provide for a physical delivery of a chemical compound to systemic circulation via various known routes of administration. Example of such forms include, oral tablets, parenteral injections, topical preparations. In the instant case "an electromagnetic memory" of a chemical agent, which is the actual therapeutic agent on the instantly claimed pharmaceutical form, is not a recognized term in the art. Neither does a person experienced in the art understand what is the common usage of such product. Thus, the claimed administration form is not a recognized pharmaceutical form. Further, specification does not provide any guidance, nor does it define the metes and bounds of such recitation.

Appellant also argues that the term "bioresonance spectrum" is well explained in page 5 of the specification and is enabling to one of skill in the art.

In response, Examiner states that the specification is void of any definition of such term. Furthermore, the art fails to specify and describe a "bioresonance spectrum," or how is it generated (see Schoni at page 238, 1st para and at 244, 5th para.)? Even though, the term "bioenergy" is recognized in the art, no association or link has ever been described in the art, or the instant specification, between "bioenergy" and "bioresonance spectrum." Thus, the recitation is vague, which renders the whole claim ambiguous. Accordingly, rejection of claim 1 should be maintained.

- **Claim 3, 4-5 should stand rejected under 35 U.S.C. 112, second paragraph, because the recitation of "skin well-tolerated adhesive tape," and "predetermined factor and amplification" render the claim as a whole indefinite.**

Appellant argues that the scope of the term "skin well-tolerated adhesive tape" is sufficiently clear and a practitioner can ascertain what type of product to use. In response Examiner states such recitations appear to be relative and variable in nature because they are associated with a degree of tolerance among various subjects and that by itself is a subjective and relative measurement. For example, a well-tolerated tape on an animal might cause an allergic reaction on a human subject when applied topically. A human neonate or a geriatric patient may not be able to tolerate such tapes.

Latex allergies, for example, are well documented in the art. A subject may be able to use a latex glove but such glove can cause a severe allergic reaction on another. Thus, the term "skin well-tolerated adhesive tape" is ambiguous because it is not clear what type of product it can encompass as it is a patient dependent measurement and thus relative in nature. Subsequently, the metes and bounds of the claim are not well defined and claim 3 should stand rejected.

With respect to the recitation of "predetermined factor" and "predetermined amplification," Appellant argues that such limitations depend on the medication used, the disease, and other circumstances, and no specific range need to be given.

In response, Examiner states that "when interpreting a claim term which is ambiguous, such as a pre-selected level of force, [one] must look to the specification for the meaning ascribed to that term by the inventor." (see MPEP 2111.01). Accordingly, if the specification had defined such term, the limitation would have been deemed

definite. In the instant case, recitations "predetermined factor" and "predetermined amplification" are ambiguous. In fact, Appellant agrees that it depends on various factors, none of which is well enumerated in the specification (see Appellant's Brief, page 4, 4th para.). Thus, absence of a clear definition within the specification, the terms are deemed indefinite.

- **Claims 1, 3-5 should stand rejected under 35 USC § 112, 1st paragraph, because the specification fails to enable any person skilled in the art to make, use, and further practice the invention without undue experimentation.**

Appellant alleges the Examiner is improperly weaving his personal belief into the support for the rejection. In response, Examiner is not clear how appellant come to such conclusion, and on what premise, legal theory or evidence is such conclusion drawn. In fact, Examiner has set forth a prima facia case analyzing the Wand Factors as described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404, Fed. Cir. 1988. Each individual factor is assessed based on the Schoni's published document in the International Archives of Allergy and Immunology; a reputable scientific journal. Appellant has not provided any evidence challenging the ambiguity in the art surrounding the instant claims, neither has appellant addressed the assessment of the factors enumerated by the Examiner. In fact, Appellant has chosen to characterize Schoni's publication as "worthless." (see Paper No. 8/B, page 4, line 8), and further relied on the descriptive statements within the instant specification.

In fact, Appellant admits that "no detailed mechanism of action can be provided at the present time." (see Brief page 6, line13). Accordingly, neither objective arguments nor scientific data are provided to rebut the rejection. Therefore, Appellant has not met

his burden of proof. Appellant argues that in seeking protection of the present invention there is no prerequisite for providing detailed mechanism of action. Accordingly, Appellant appears to argue that such methods are understood in the art and is achievable by routine experimentation. In response, Examiner states that 35 USC § 112, 1st requires the specification in question to provide a reasonable amount of guidance, or direction, in which experimentation should proceed in order to make, and use, the invention. In the instant case, no guidance is provided as what type of spectrum exists on the claimed tape, how is it associated to its respective therapeutic benefits, and how the claimed method provides a therapeutic treatment. In the instant Appliation all descriptions are prophetic.

Accordingly, assuming *arguendo* that such questions may be answered by routine experimentation, the great quantity of experimentation that is required to associate the claimed "bioresonace spectrum" of a chemical compound to the specific treatment method, accrues to an undue level of experimentation. Thus, Appellant has failed to meet his burden, and claims 1, 3-5 should stand rejected.

- **Claim 1 should stand rejected under 35 U.S.C. 102(b) as being anticipated by Berner et al DE 3419055, because Brenner discloses a magnetic foil sheet comprising magnetic particles which meets the limitations of the instant claim.**

Appellant argues that Brenner does not teach the bioresonance spectrum of a medical compound. In response Examiner states that Zinc or Copper metals are considered medical compounds within the definition of the claimed medical compound, because they have various therapeutic utility and are provided in pharmaceutical

dosage forms as dietary supplements or cough and cold lozenges. Accordingly, appellant's assessment of medical compound is not accurate.

Appellant also argues that Brenner does not disclose the instantly claimed frequencies. In response, as Examiner has stated throughout the prosecution, the instant claim appears to be drafted in the form of a product-by-process, accordingly, any tape containing a electromagnetic spectrum anticipates the instant claims. Thus, the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as, or obvious, over a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

In the instant case, Brenner discloses a magnetic foil sheet for biophysical therapy comprising a plastic matrix and magnetic particles (see abstract). Anticipation in this case is independent of its method of production; thus, Brenner meets the limitations of the instant claim.

- **Claims 1, 3 and 5 should stand rejected under 35 U.S.C. 102(b) as being anticipated by Whitson-Fischman US Patent 5,162,037 because Whitson-Fischmann discloses methods of impregnating a topical patch comprising a homeopathic medicament and a magnetically permeable ingredient that is magnetized.**

Appellant argues that Whitson-Fischman is directed to a magnetic tape are made of porous material capable of absorbing a therapeutic amount of homeopathic medicament. In response Examiner replies that Whitson-Fischmann teaches magnetic patches and methods of using such patches by aligning it near a selected acupuncture point on the patient's skin (see abstract; col 6 lines 35-68; col 7 lines 1-30; examples

25-38; col 9 lines 29-61, col 40 lines 16-40). Again, the product claims are anticipated as they are drafted in the form of product-by-process claims. Further, Whitson-Fischmann passes his medicament through a magnetic field apparatus, meeting the requirement of the instant resonance generator (see examples 3).

Finally, the instant claims do not exclude any porous material or products that do not absorb any therapeutic amount of homeopathic medicament. Thus, Appellant's arguments are not commensurate in scope of the pending claims and Whitson-Fischmann meets the limitations set forth in the instant claims.

- **Claims 1, 3-5 rejected under 35 U.S.C. 102(e) as being anticipated by Dillinger et al US Patent 5,830,140 because Dillinger et al discloses the use of a bioresonance apparatus to register the substance specific or body specific energetic information in the form of electromagnetic spectra to produce a homeopathic medicament composition.**

Appellant argues that Dillinger teaches away from the present invention by using a complicated apparatus to administer the medication to the patient as opposed to the instant invention where conventional videotapes and the like may be adhered to the body. Again, Appellant's arguments are not commensurate with the scope of the claims, as the instant claims fail to exclude any added medications.

Dillinger discloses medicaments for direct application to human body (see col 3, lines 12-15; col 1 lines 1-65, col 3 lines 40-67, col 4 lines 65-67). The medicaments are prepared using the apparatus described in Dillinger. The apparatus described in Dellinger operates in substantially the same manner to prepare the instant products as those used in the instant specification. Thus, Dellinger's medicamented compositions comprise all wave frequency associated properties and characteristics as those

instantly claimed. Accordingly, Dillinger et al meet the limitations set forth in the instant claims.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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